PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
1038-939 MIS		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/CA 99/ 00292	07/04/1999	07/04/1998
Applicant		
UNIVERSITY OF MANITOBA et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[X] furnished subsequently to this Authority in written form.

[X] furnished subsequently to this Authority in computer readble form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[X] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

[ ] as suggested by the applicant.

[ ] because the applicant failed to suggest a figure.

[ ] because this figure better characterizes the invention.

[ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 99/ 00292

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 16-33 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]T/CA 99/00292

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C12N15/31 C07K14/295 A61K31/70 A61K39/118

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) cited in the application the whole document especially page 10 lines 4-10 ---	1-35
A	DONNELLY J J ET AL: "PROTECTIVE EFFICACY OF INTRAMUSCULAR IMMUNIZATION WITH NAKED DNA" ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, vol. 772, 1 January 1995 (1995-01-01), pages 40-46, XP000576178 --- -/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 October 1999	13/10/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ceder, O

1

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	YOU-XUN ZHANG ET AL: "COMPARISON OF THE MAJOR OUTER-MEMBRANE PROTEIN (MOMP) GENE OF MOUSEPNEUMONITIS (MOPN) AND HAMSTER SFPD STRAINS OF CHLAMYDIA TRACHOMATIS WITH OTHER CHLAMYDIA STRAINS" MOLECULAR BIOLOGY AND EVOLUTION, vol. 10, no. 6, 1 November 1993 (1993-11-01), pages 1327-1342, XP000561977 ISSN: 0737-4038	

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
T/CA 99/00292

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802546 A	22-01-1998	AU 3431497 A	09-02-1998
		CA 2259595 A	22-01-1998
		EP 0915978 A	19-05-1999

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
C12N 15/31, C07K 14/295, A61K 31/70, 39/118

A3

(11) International Publication Number: WO 99/51745

(43) International Publication Date: 14 October 1999 (14.10.99)

(21) International Application Number: PCT/CA99/00292

(22) International Filing Date: 7 April 1999 (07.04.99)

(30) Priority Data:
09/055,765 7 April 1998 (07.04.98) US

(71) Applicant *(for all designated States except US)*: UNIVERSITY OF MANITOBA [CA/CA]; Dept. of Medical Microbiology, Room 543, 730 William Avenue, Winnipeg, Manitoba R3E 0W3 (CA).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: BRUHNAM, Robert, C. [CA/CA]; University of Manitoba, Dept. of Medical Microbiology, Room 543, 730 William Avenue, Winnipeg, Manitoba R3E 0W3 (CA).

(74) Agent: STEWART, Michael, I.; Sim & McBurney, 6th floor, 330 University Avenue, Toronto, Ontario M5G 1R7 (CA).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:
2 December 1999 (02.12.99)

(54) Title: DNA IMMUNIZATION AGAINST *CHLAMYDIA* INFECTION

(57) Abstract

Nucleic acid, including DNA, for immunization to generate a protective immune response in a host, including humans, to a major outer membrane protein of a strain of *Chlamydia*, preferably contains a nucleotide sequence encoding a fragment that generates antibodies that specifically react with MOMP and a promoter sequence operatively coupled to the first nucleotide sequence for expression of the MOMP fragment in the host. The non-replicating vector may be formulated with a pharmaceutically-acceptable carrier for *in vivo* administration to the host.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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EE	Estonia	**LR**	Liberia	**SG**	Singapore		

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 99/00292

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C12N15/31 C07K14/295 A61K31/70 A61K39/118

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) cited in the application the whole document especially page 10 lines 4-10 ---	1-35
A	DONNELLY J J ET AL: "PROTECTIVE EFFICACY OF INTRAMUSCULAR IMMUNIZATION WITH NAKED DNA" ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, vol. 772, 1 January 1995 (1995-01-01), pages 40-46, XP000576178 --- -/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 October 1999	13/10/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ceder, O

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	YOU-XUN ZHANG ET AL: "COMPARISON OF THE MAJOR OUTER-MEMBRANE PROTEIN (MOMP) GENE OF MOUSEPNEUMONITIS (MOPN) AND HAMSTER SFPD STRAINS OF CHLAMYDIA TRACHOMATIS WITH OTHER CHLAMYDIA STRAINS" MOLECULAR BIOLOGY AND EVOLUTION, vol. 10, no. 6, 1 November 1993 (1993-11-01), pages 1327-1342, XP000561977 ISSN: 0737-4038	

INTERNATIONAL SEARCH REPORT

national application No.
PCT/CA 99/ 00292

Box I Observations where certain claims were found unsearchable (Continuation f item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 16-33 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

[redacted]nformation on patent family members

Int[redacted]nal Application No
PCT/CA 99/00292

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802546 A	22-01-1998	AU 3431497 A	09-02-1998
		CA 2259595 A	22-01-1998
		EP 0915978 A	19-05-1999

CLAIMS

What I claim is:

1. A non-replicating vector, comprising:

a nucleotide sequence encoding a region comprising at least one of the conserved domains 2, 3 and 5 of a major outer membrane protein of a strain of *Chlamydia*, and

a promoter sequence operatively coupled to said nucleotide sequence for expression of said at least one conserved domain in a host.

2. The vector of claim 1 wherein said nucleotide sequence encoding the conserved domain 2 and/or 3 further includes a nucleotide sequence encoding a variable domain of the major outer membrane protein immediately downstream of the conserved domain.

3. The vector of claim 1 wherein said nucleotide sequence encodes the conserved domain 5 of the outer membrane protein.

4. The vector of claim 1 wherein said promoter sequence is the cytomegalovirus promoter.

5. The vector of claim 1 wherein said non-replicating vector comprises plasmid pcDNA3 containing said promoter sequence and into wherein said nucleotide sequence is inserted in operative position to said promoter sequence.

6. The vector of claim 5 wherein said strain of *Chlamydia* is a strain producing chlamydial infectious of the lung.

7. The vector of claim 5 wherein said strain of *Chlamydia* is a strain of *Chlamydia trachomatis*.

8. An immunogenic composition for *in vivo* administration to a host for the generation in the host of a protective immune response to a fragment of a major outer membrane protein (MOMP) of a strain of *Chlamydia*, comprising a non-replicating vector comprising:

a nucleotide sequence encoding a region comprising at least one of the conserved domains 2, 3 and 5 of a major

outer membrane protein of a strain of *Chlamydia* and that generates a MOMP-specific immune response, and

a promoter sequence operatively coupled to said nucleotide sequence for expression of said MOMP or MOMP fragment in the host; and

a pharmaceutically-acceptable carrier therefor.

9. The immunogenic composition of claim 8 wherein said nucleotide sequence encoding the conserved domain 2 and/or 3 further includes a nucleotide sequence encoding a variable domain of the major outer membrane protein immediately downstream of said conserved domain.

10. The immunogenic composition of claim 8 wherein said nucleotide sequence encodes the conserved domain 5 of a major outer membrane protein of a strain of *Chlamydia*.

11. The immunogenic composition of claim 8 wherein said promoter sequence is the cytomegalovirus promoter.

12. The immunogenic composition of claim 1 wherein said strain of *Chlamydia* is a strain producing chlamydial infections of the lung.

13. The immunogenic of claim 8 wherein said strain of *Chlamydia* is a strain of *Chlamydia trachomatis*.

14. The immunogenic composition of claim 13 wherein said non-replicating vector comprises plasmid pcDNA3 containing said promoter sequence and into which said nucleotide sequence is inserted in operative relation to said promoter sequence.

15. The composition of claim 8 wherein said immune response is predominantly a cellular immune response.

16. A method of immunizing a host against disease caused by infection with a strain of *Chlamydia*, which comprises administering to said host an effective amount of a non-replicating vector comprising:

a nucleotide sequence encoding a a region comprising at least one of the conserved domains 2, 3 and 5 of a

major outer membrane protein of a strain of *Chlamydia* and that generates a MOMP-specific immune response, and

a promoter sequence operatively coupled to said nucleotide sequence for expression of said MOMP in the host.

17. The method of claim 16 wherein said promoter sequence is the cytomegalovirus promoter.

18. The method of claim 16 wherein said strain of *Chlamydia* is a strain producing chlamydial infections of the lung.

19. The method of claim 16 wherein said strain of *Chlamydia* is a strain of *Chlamydia trachomatis*.

20. The method of claim 16 wherein said non-replicating vector comprises plasmid pcDNA3 containing said promoter into which said nucleotide sequence is inserted in operative relation to said promoter sequence.

21. The method of claim 16 wherein said immune response is predominantly a cellular immune response.

22. The method of claim 16 wherein said non-replicating vector is administered intranasally.

23. The method of claim 16 wherein said host is a human host.

24. A method of using a nucleotide sequence encoding a fragment of a major outer membrane protein (MOMP) of a strain of *Chlamydia* that generates a MOMP-specific immune response, to produce an immune response in a host, which comprises:

isolating said nucleotide sequence encoding a region comprising at least one of the conserved domains 2, 3 and 5 of a major outer membrane protein of a strain of *Chlamydia*,

operatively linking said nucleotide sequence to at least one control sequence to produce a non-replicating vector, said control sequence directing expression of said

MOMP fragment when introduced into a host to produce an immune response to said MOMP fragment, and

introducing said vector into a host.

25. The method of claim 24 wherein said nucleotide sequence encoding the conserved domain 2 and/or 3 further includes a nucleotide sequence encoding a variable domain of the major outer membrane protein immediately downstream of said conserved domain.

26. The method of claim 24 wherein said nucleotide sequence encodes the conserved domain 5 of a major outer membrane protein of a strain of *Chlamydia*.

27. The method of claim 24 wherein said control sequence is the cytomegalovirus promoter.

28. The method of claim 24 wherein said strain of *Chlamydia* is a strain producing chlamydial infections of the lung.

29. The method of claim 24 wherein said strain of *Chlamydia* is a strain of *Chlamydia trachomatis*.

30. The method of claim 24 wherein said non-replicating vector comprises plasmid pcDNA3 containing said control sequence into which said gene encoding MOMP is inserted in operative relation to said control sequence.

31. The method of claim 24 wherein said immune response is predominantly a cellular immune response.

32. The method of claim 24 wherein said vector is introduced into said host intranasally.

33. The method of claim 24 wherein said host is a human host.

34. A method of producing a vaccine for protection of a host against disease caused by infection with a strain of *Chlamydia*, which comprises:

isolating a nucleotide sequence encoding a a region comprising at least one of the conserved domains 2, 3 and 5 of a major outer membrane protein of a strain of

Chlamydia and that generates a MOMP-specific immune response,

operatively linking said nucleotide sequence to at least one control sequence to produce a non-replicating vector, the control sequence directing expression of said MOMP fragment when introduced to a host to produce an immune response to said MOMP fragment, and

formulating said vector as a vaccine for *in vivo* administration to a host.

35. A vaccine produced by the method of claim 34.

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PATENT COOPERATION TREATY

REC'D 18 JUL 2000
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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
1038-939 MIS		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/00292	07/04/1999	07/04/1998
International Patent Classification (IPC) or national classification and IPC C12N15/31		
Applicant UNIVERSITY OF MANITOBA et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02/11/1999	13.07.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Zellner, E Telephone No. +49 89 2399 8427

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00292

I. Basis f th r p rt

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-31 as originally filed

Claims, No.:

1-35 as received on 07/04/2000 with letter of 07/04/2000

Drawings, sheets:

1/15-15/15 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-35
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-35
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-35
	No:	Claims	

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Item V

D1: WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) cited in the application

1. Present Claims 1-35 appear to be novel and inventive in view of the prior art cited in the International Search Report.. Said claims refer to "... a nucleotide sequence encoding a region which is **at least one** of the conserved domains 2, 3 and 5 of a major outer membrane protein of a strain of Chlamydia...for expression of **at least one** conserved domain in a host.
In D1 the entire outer membrane protein MOMP or the half of the N-terminal fragment of MOMP is expressed and applied in vaccination.
In said document no particular domain of MOMP is mentioned or identified.

The claimed constructs are useful for immunization against Chlamydia. In difference to the plasmid of D1 the vectors containing specific segments of the MOMP gene were able to elicit a greater response comparable to the entire MOMP (page 23, line 27-32).

3. For the assessment of the present claims 16-33 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Item VIII

The domains of Claims 1, 8, 16, 24 and 34 are not defined such as in the description page 4, lines 11-16. A skilled person does not know which amino acids are encompassed by the domains. Therefore said claims are not clear (Article 6 PCT).

Attention is drawn to the fact that if plasmids are included into the claims, said plasmids have to be defined such as by a reference to Figure 2.

PATENT COOPERATION TREATY

by fax and post

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

STEWART Michael I.
Sim & McBurney
330 University Avenue
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Toronto, Ontario M5G 1R7
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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	13.07.2000
Applicant's or agent's file reference: 1038-939 MIS	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/00292	07/04/1999	07/04/1998

Applicant
UNIVERSITY OF MANITOBA et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Büchler, S Tel.+49 89 2399-8090

Form PCT/IPEA/416 (July 1992)

P NT COOPERATION TREAT

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
1038-939 MIS		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/00292	07/04/1999	07/04/1998
International Patent Classification (IPC) or national classification and IPC		
C12N15/31		
Applicant		
UNIVERSITY OF MANITOBA et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02/11/1999	13.07.2000
Name and mailing address of the international preliminary examining authority:	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Zellner, E Tel phone No. +49 89 2399 8427

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00292

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-31 as originally filed

Claims, No.:

1-35 as received on 07/04/2000 with letter of 07/04/2000

Drawings, sheets:

1/15-15/15 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00292

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 1-35
	No:	Claims
Inventive step (IS)	Yes:	Claims 1-35
	No:	Claims
Industrial applicability (IA)	Yes:	Claims 1-35
	No:	Claims

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Item V

D1: WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) cited in the application

1. Present Claims 1-35 appear to be novel and inventive in view of the prior art cited in the International Search Report.. Said claims refer to "... a nucleotide sequence encoding a region which is **at least one** of the conserved domains 2, 3 and 5 of a major outer membrane protein of a strain of Chlamydia...for expression of **at least one** conserved domain in a host.
In D1 the entire outer membrane protein MOMP or the half of the N-terminal fragment of MOMP is expressed and applied in vaccination.
In said document no particular domain of MOMP is mentioned or identified.

The claimed constructs are useful for immunization against Chlamydia. In difference to the plasmid of D1 the vectors containing specific segments of the MOMP gene were able to elicit a greater response comparable to the entire MOMP (page 23, line 27-32).

3. For the assessment of the present claims 16-33 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

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The domains of Claims 1, 8, 16, 24 and 34 are not defined such as in the description page 4. lines 11-16. A skilled person does not know which amino acids are encompassed by the domains. Therefore said claims are not clear (Article 6 PCT).

Attention is drawn to the fact that if plasmids are included into the claims, said plasmids have to be defined such as by a reference to Figure 2.

CLAIMS

What I claim is:

1. A non-replicating vector, comprising:

a nucleotide sequence encoding a region which is at least one of the conserved domains 2, 3 and 5 of a major outer membrane protein of a strain of *Chlamydia*, and

a promoter sequence operatively coupled to said nucleotide sequence for expression of said at least one conserved domain in a host.

2. The vector of claim 1 wherein said nucleotide sequence encoding the conserved domain 2 and/or 3 further includes a nucleotide sequence encoding a variable domain of the major outer membrane protein immediately downstream of the conserved domain.

3. The vector of claim 1 wherein said nucleotide sequence encodes the conserved domain 5 of the outer membrane protein.

4. The vector of claim 1 wherein said promoter sequence is the cytomegalovirus promoter.

5. The vector of claim 1 wherein said non-replicating vector comprises plasmid pcDNA3 containing said promoter sequence and into wherein said nucleotide sequence is inserted in operative position to said promoter sequence.

6. The vector of claim 5 wherein said strain of *Chlamydia* is a strain producing chlamydial infectious of the lung.

7. The vector of claim 5 wherein said strain of *Chlamydia* is a strain of *Chlamydia trachomatis*.

8. An immunogenic composition for *in vivo* administration to a host for the generation in the host of a protective immune response to a fragment of a major outer membrane protein (MOMP) of a strain of *Chlamydia*, comprising a non-replicating vector comprising:

a nucleotide sequence encoding a region which is at least one of the conserved domains 2, 3 and 5 of a major

outer membrane protein of a strain of *Chlamydia* and that generates a MOMP-specific immune response, and

a promoter sequence operatively coupled to said nucleotide sequence for expression of said MOMP or MOMP fragment in the host; and

a pharmaceutically-acceptable carrier therefor.

9. The immunogenic composition of claim 8 wherein said nucleotide sequence encoding the conserved domain 2 and/or 3 further includes a nucleotide sequence encoding a variable domain of the major outer membrane protein immediately downstream of said conserved domain.

10. The immunogenic composition of claim 8 wherein said nucleotide sequence encodes the conserved domain 5 of a major outer membrane protein of a strain of *Chlamydia*.

11. The immunogenic composition of claim 8 wherein said promoter sequence is the cytomegalovirus promoter.

12. The immunogenic composition of claim 1 wherein said strain of *Chlamydia* is a strain producing chlamydial infections of the lung.

13. The immunogenic of claim 8 wherein said strain of *Chlamydia* is a strain of *Chlamydia trachomatis*.

14. The immunogenic composition of claim 13 wherein said non-replicating vector comprises plasmid pcDNA3 containing said promoter sequence and into which said nucleotide sequence is inserted in operative relation to said promoter sequence.

15. The composition of claim 8 wherein said immune response is predominantly a cellular immune response.

16. A method of immunizing a host against disease caused by infection with a strain of *Chlamydia*, which comprises administering to said host an effective amount of a non-replicating vector comprising:

a nucleotide sequence encoding a region which is at least one of the conserved domains 2, 3 and 5 of a major

outer membrane protein of a strain of *Chlamydia* and that generates a MOMP-specific immune response, and

a promoter sequence operatively coupled to said nucleotide sequence for expression of said MOMP in the host.

17. The method of claim 16 wherein said promoter sequence is the cytomegalovirus promoter.

18. The method of claim 16 wherein said strain of *Chlamydia* is a strain producing chlamydial infections of the lung.

19. The method of claim 16 wherein said strain of *Chlamydia* is a strain of *Chlamydia trachomatis*.

20. The method of claim 16 wherein said non-replicating vector comprises plasmid pcDNA3 containing said promoter into which said nucleotide sequence is inserted in operative relation to said promoter sequence.

21. The method of claim 16 wherein said immune response is predominantly a cellular immune response.

22. The method of claim 16 wherein said non-replicating vector is administered intranasally.

23. The method of claim 16 wherein said host is a human host.

24. A method of using a nucleotide sequence encoding a fragment of a major outer membrane protein (MOMP) of a strain of *Chlamydia* that generates a MOMP-specific immune response, to produce an immune response in a host, which comprises:

isolating said nucleotide sequence encoding a region which is at least one of the conserved domains 2, 3 and 5 of a major outer membrane protein of a strain of *Chlamydia*,

operatively linking said nucleotide sequence to at least one control sequence to produce a non-replicating vector, said control sequence directing expression of said

MOMP fragment when introduced into a host to produce an immune response to said MOMP fragment, and

introducing said vector into a host.

25. The method of claim 24 wherein said nucleotide sequence encoding the conserved domain 2 and/or 3 further includes a nucleotide sequence encoding a variable domain of the major outer membrane protein immediately downstream of said conserved domain.

26. The method of claim 24 wherein said nucleotide sequence encodes the conserved domain 5 of a major outer membrane protein of a strain of *Chlamydia*.

27. The method of claim 24 wherein said control sequence is the cytomegalovirus promoter.

28. The method of claim 24 wherein said strain of *Chlamydia* is a strain producing chlamydial infections of the lung.

29. The method of claim 24 wherein said strain of *Chlamydia* is a strain of *Chlamydia trachomatis*.

30. The method of claim 24 wherein said non-replicating vector comprises plasmid pcDNA3 containing said control sequence into which said gene encoding MOMP is inserted in operative relation to said control sequence.

31. The method of claim 24 wherein said immune response is predominantly a cellular immune response.

32. The method of claim 24 wherein said vector is introduced into said host intranasally.

33. The method of claim 24 wherein said host is a human host.

34. A method of producing a vaccine for protection of a host against disease caused by infection with a strain of *Chlamydia*, which comprises:

isolating a nucleotide sequence encoding a a region which is at least one of the conserved domains 2, 3 and 5 of a major outer membrane protein of a strain of *Chlamydia* and that generates a MOMP-specific immune response,

operatively linking said nucleotide sequence to at least one control sequence to produce a non-replicating vector, the control sequence directing expression of said MOMP fragment when introduced to a host to produce an immune response to said MOMP fragment, and

formulating said vector as a vaccine for in vivo administration to a host.

35. A vaccine produced by the method of claim 34.